

Louisiana Medicaid
Tafamidis (Vyndamax™) / Tafamidis Meglumine (Vyndaqel®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tafamidis (Vyndamax™) and tafamidis meglumine (Vyndaqel®).

Additional Point-of-Sale edits may apply.

*These agents may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) confirmed by definitive tests [dates, type of testing, and results are **stated on the request**]; **AND**
- The recipient exhibits clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction); **AND**
- The recipient has a medical history of heart failure with at least one prior hospitalization for heart failure within 12 months prior to the date of the request [**List most recent date of hospitalization**]; **AND**
- The recipient does **NOT** have a diagnosis of New York Heart Association (NYHA) class IV heart failure; **AND**
- Tafamidis (Vyndamax™) / tafamidis meglumine (Vyndaqel®) is prescribed by, or the request states that the medication is being prescribed in consultation with, a cardiologist or physician who specializes in the treatment of amyloidosis; **AND**
- By submitting the authorization request, the prescriber attests to the following;
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of tafamidis (Vyndamax™) / tafamidis meglumine (Vyndaqel®); **AND**
 - Tafamidis (Vyndamax™) / tafamidis meglumine (Vyndaqel®) will not be used in combination with any medication that is contraindicated or not recommended per FDA labeling.

NOTE: Vyndaqel® and Vyndamax™ are not substitutable on a per mg basis.

Reauthorization Criteria

- The recipient continues to meet initial diagnosis, age, and heart failure classification approval criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by either maintenance of the current condition or improvement in signs and symptoms compared to baseline (e.g. improved cardiac function, quality of life, slowing of disease progression, decreased hospitalizations).

Duration of initial and reauthorization approval: 12 months

References

Donnelly JP, Hanna M. cardiac amyloidosis: an update on diagnosis and treatment. Cleve Clin J Med. 2017;84(12 Suppl 3):12-26. https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/hanna_cardiacamyloidosis.pdf

Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11): 1007-1016. https://www.nejm.org/doi/10.1056/NEJMoa1805689?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, ant treatment. Trends Cardiovasc Med. 2018;28(1):10-21. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741539/>

Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis) [package insert]. New York, NY: Pfizer Labs; May 2019. <https://www.fda.gov/media/126283/download>

Revision / Date	Implementation Date
Policy created / October 2019	March 2020
Removed POS wording, formatting changes, updated references /May 2021	January 2022